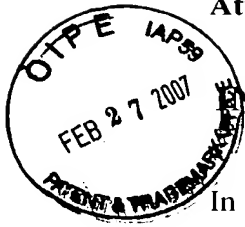


IFW/631

Attorney Docket No. GENE-035/09US

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MENDRICK *et al.*

Confirmation No.: 1108

Serial No.: 09/917,800

Group Art Unit: 1631

Filed: July 31, 2001

Examiner: M. I. Miller

For: MOLECULAR TOXICOLOGY MODELING

U.S. Patent and Trademark Office
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Alexandria, VA 22314

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08 for the above-identified patent application.

- ☐ In accordance with 37 C.F.R. §1.97(c), also enclosed is:
- ☐ the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
 - ☐ a statement as specified in 37 C.F.R. §1.97(e).
- ☒ A return receipt postcard is also enclosed.
- ☐ Please charge \$180.00 to Deposit Account No. 50-1283 for the total fee. This paper is being submitted in duplicate.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Respectfully submitted,
COOLEY GODWARD LLP

Dated: February 27, 2007

By:

Hong Lin for
(Hong Lin, Reg. # 54,891)
Michael S. Tuscan
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re Application of MENDRICK *et al.*

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(c)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- ☒ Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form PTO/SB/08 is enclosed.
- ☒ No copies of any U.S. patents or U.S. patent application publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- ☒ The present application and its related applications generally disclose toxicology modeling of various tissues or cells, *e.g.*, heart, kidney, liver, or primary hepatocytes using gene expression data. As such, some of the nucleic acid sequences disclosed in this application may overlap with those disclosed in other related applications. For the Examiner's convenience, a list of the co-pending applications is presented below.

| APPLICATION SERIAL NO. | TITLE | APPLICATION DATE | TISSUE |
|---------------------------|---|---------------------|--------|
| 09/917,800 | Molecular Toxicology Modeling | July 31, 2001 | Liver |
| 10/501,933 | Molecular Hepatotoxicology Modeling | Jan. 31, 2003 | Liver |

| APPLICATION SERIAL NO. | TITLE | APPLICATION DATE | TISSUE |
|------------------------|--|------------------|------------|
| 11/059,535 | Molecular Toxicology Modeling | Feb. 17, 2005 | Liver |
| 10/152,319 | Molecular Toxicology Modeling | May 22, 2002 | Kidney |
| 10/515,325 | Molecular Nephrotoxicology Modeling | Nov. 24, 2003 | Kidney |
| 11/036,196 | Molecular Toxicology Modeling | Jan. 18, 2005 | Kidney |
| 11/642,647 | Molecular Nephrotoxicology Modeling | Dec. 21, 2006 | Kidney |
| 10/338,044 | Molecular Cardiotoxicology Modeling | Jan. 8, 2003 | Heart |
| 10/541,937 | Molecular Cardiotoxicology Modeling | Jan. 8, 2004 | Heart |
| 11/600,759 | Cardiotoxin Molecular Toxicology Modeling | Nov. 17, 2006 | Heart |
| 10/357,507 | Primary Rat Hepatocyte Toxicology Modeling | Feb. 4, 2003 | Hepatocyte |
| 10/515,373 | Primary Rat Hepatocyte Toxicity Modeling | Aug. 9, 2004 | Hepatocyte |
| 10/580,423 | Methods For Molecular Toxicology Modeling | Nov. 24, 2004 | General |
| 11/547,759 | Hepatotoxicity Molecular Models | Apr. 7, 2005 | Liver |

[X] In particular, the following publications were cited by the U.S. Patent Examiner in U.S. application 09/917,800:

1. U.S. 5,811,231
2. U.S. 6,372,431
3. U.S. 6,218,122
4. Lashkari *et al.* PNAS, vol. 94: 13057-13062, 1997

[X] The following publications were cited by the Examiner in U.S. application 10/152,319:

1. "nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at <http://www.m-w.com/cgi-bin/dictionary?Book=Dictionary&va=nephrotoxic>

2. Yamaki *et al.* Cellular mechanism of lithium-induced nephrogenic diabetes insipidus in rats. American Journey of Physiology Renal Physiology, 1991. Vol. 261, F505-F511

[X] The following publication was cited by the Examiner in U.S. application 10/301,856:

1. Konstandi *et al.* Stress-mediated modulation of B(alpha)P-induced hepatic CYP1A1: role of catechomaines, 2004 Chemico-Biological Interactions, vol. 147

[X] The following publication was cited by the Examiner in U.S. application 10/191,803:

U.S. 6,461,807

[X] The following publications were cited by the Examiner in U.S. application 10/357,507:

1. U.S. 6,203,987
2. Peng *et al.* JBC, 271(6):3324-3327
3. GenBank Acc. No. AA799479 (4/30/1998)
4. GenBank Acc. No. AI177366 (1/20/1999)
5. GenBank Acc. No. M25823 (4/27/1993)
6. GenBank Acc. No. AA891812 (1/25/1999)

[X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US01/23872.

1. Raburn *et al.*, "Stage-specific expression of B Cell Translocation Gene 1 in rat testis," Endocrinology 136(12):5769 - 5777, 1995
2. GenBank Accession No. L26268, Raburn *et al.*, "Rattus norvegicus anti-proliferative factor (BTG1) mRNA," January 26, 1996
3. Bissig *et al.*, "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," J Biol. Chem 269(4):3017-3021, 1994
4. GenBank Accession No. L23413, Bissig *et al.*, "Rattus norvegicus sulfate anion transporter (sat-1) mRNA," April 12, 1994
5. WO 00/12760

6. Farr *et al.*, "Concise review: gene expression applied to toxicology," *Toxicol Sci* 50(1):1-9, 1999
7. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153 - 159, 1999

[X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US02/21735.

1. US 2001/0039006 A1
2. US 2002/0119462 A1
3. Grigg *et al.* Environmental Health Institute to use gene chips to evaluate chemicals for potential harm to humans. NIEHS, 29 February 2000
4. US 6,228,589

[X] The following publications were cited in a foreign search or examination report corresponding to EP 01959321.9.

1. Markovich *et al.*, "Heavy metals mercury, cadmium, and chromium inhibit the activity of the mammalian liver and kidney sulfate transporter sat-1," *Toxicol. Appl. Pharmacol.* 154:181-187 (1999)
2. WO 99/58670
3. WO 93/01205
4. WO 99/43345
5. Berbner *et al.*, "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (*Onchorhynchus mykiss*) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," *Biomarkers* 4: 214-228 (1999)
6. Bogdan, "Human carbon catabolite repressor protein (CCR4)-associative factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," *Biochem. J.* 336:471-481 (1998)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/03194:

1. U.S. 6,218,122
2. U.S. 2001/0049139

[X] The following publications were cited in a foreign search or examination report corresponding to Canadian application 2,447,357

1. WO 01/32928, 05/11/01, Far *et al.*
2. Fielden *et al.* Changes and limitations of gene expression profiling in mechanistic and predictive toxicology, *Toxicol. Sci.* 60: 6-10
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[X] The following publications were cited in a foreign search or examination report corresponding to EP 02771863.4

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US02/16173:

1. U.S. 6,228,589
2. U.S. 6,365,352
3. U.S. 6,403,778
4. Kim *et al.*, Fumonisin B1 induces apoptosis in LLC-PK1 renal epithelial cells via a sphinganine and calmodulin dependent pathway. *Toxicology and Applied Pharmacology* 176:118-126 (2001)

5. Yang *et al.*, Differential regulation of COX-2 expression in the kidney by lipopolysacc: role of CD14. *Am J Physiology* 277(1):F10-F16 (1999)
6. Pfeffer *et al.*, Xanthine dehydrogenase and xanthine oxidase activity and gene expression in renal epithelial cells. *J Immunology* 153(4):1789-1797 (1994)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/37556:

1. U.S. Publication 2002/0142284, 10/03/2002, Raha *et al*
2. WO 94/17208
3. WO 97/13877

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02806804.7

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/025646:

1. Wilson, *et al.* Exploring drug-induced alterations in gene expression in mycobacterium tuberculosis by microarray hybridization. PNAS 96:12833-12838 (1999)
2. Tao, *et al.*, Profiling of differently expressed apoptosis-related genes by cDNA arrays in human cord blood DC34+ cells treated with etoposide. Experimental Hematology, 31:251-2606 (2003)
3. Cadet, *et al.*, Distinct gene expression signatures in the striata of wild-type and heterozygous c-fos knockout mice following methamphetamine administration, Synapse, 44:211-2268 (2002)
4. He *et al.*, Histone deacetylase inhibitors induce remission in transgenic models of therapy-resistant acute promyelocytic leukemia., J. Biol. Chem., 276: 20858-20865 (2001)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/039593:

1. U.S. Publication 2003/0124552, 07/03/2003, Lindemann *et al*
2. U.S. 6,132,969, 02/17/2000, Stoughton *et al.*
3. U.S. 2003/0154032, 08/14/2003, Pittman *et al.*
4. U.S. 2003/0028327, 02/06/2003, Brunner *et al.*
5. Hasegawa *et al.* Gan To Kagaku Ryoho 30: 325-33 (abstract)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/034780:

1. Boorman *et al.*, "Toxicogenomics, Drug Discovery, and the Pathologist," Toxicologic Pathology 30(1):15-27 (2002).
2. Harris *et al.*, "Comparison of basal gene expression profiles and effects of hepatocarcinogens on gene expression in cultured primary human hepatocytes and HepG2 cells," Mutation Research 539:79-99 (2004).
3. Gooderham *et al.*, "Molecular and genetic toxicology of 2-amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine (PhIP)," Mutation Research 506-507:91-99 (2001).
4. Hogstrand *et al.*, "Application of genomics and proteomics for study of the integrated response to zinc exposure in a non-model fish species, the rainbow trout," Comparative Biochemistry and Physiology Part B 133:523-535 (2002).

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/011532:

1. Kikuchi *et al.* Gene expression and activities of protein phosphatases 1 alpha, 2A, 2C in hepatocarcinogenesis and regeneration after partial hepatectomy. *Cancer detection and prevention*. 1997 vol.21(1): 36-43
2. Frazier *et al.* Predictive toxicodynamics: empirical/mechanistic approaches. *Toxicology in Vitro*, 1997, vol. 11: 465-472
3. Irizarry *et al.* Summaries of Affymetrix Gene Chip probe level data. *Nucleic Acids Research*, 2003, vol. 31, page e15
4. U.S. 6,153,421
5. U.S. 6,421,612
6. U.S. 5,858,659
7. Jakubczak *et al.* An oncolytic adenovirus selective for retinoblastoma tumor suppressor protein pathway-defective tumors. *Cancer Research*, 2003 vol 63:1490-1499

This Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of:

- ☐ a final action under 37 C.F.R. §1.113;
- ☐ a notice of allowance under 37 C.F.R. §1.311; or
- ☐ an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

- ☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$180.00; or
- ☐ Statement as specified in 37 C.F.R. §1.97(e):
 - ☐ Each item of information contained in the Information Disclosure Statement cited herein was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
 - ☐ No item of information contained in the Information Disclosure Statement submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure

Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08 to the undersigned.

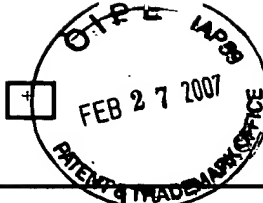
Respectfully submitted,
COOLEY GODWARD LLP

Dated: February 27, 2007

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By: Hong Liu for
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Approved for use through 07/31/2006. OMB 0651-0031

PTO/SB/08A (07-05)

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i> | | Complete if Known | |
| | | Application Number | 09/917,800 |
| | | Filing Date | 07/31/01 |
| | | First Named Inventor | MENDRICK |
| | | Group Art Unit | 1631 |
| Examiner Name | M. I. Miller | | |
| Sheet | 1 of 24 | Attorney Docket Number | GENE-035/09US |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|----------|----------------------|----------------------|---|--|
| Examiner Initials* | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY |
| | | Number | Kind Code (if known) | | |
| | 1. | 5,811,231 | | Farr et al. | 09-22-1998 |
| | 2. | 5,858,659 | | Sapolsky et al. | 01-12-1999 |
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| | 5. | 6,203,987 | | Friend et al. | 03-20-2001 |
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| | 8. | 6,365,352 | | Yerramilli et al. | 04-2-2002 |
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| | 15. | 2002/0119462 | | Mendrick et al. | 8-29-2002 |
| | 16. | 2002/0142284 | | Raha et al. | 11-3-2002 |
| | 17. | 2003/0124552 | | Lindemann et al. | 07-03-2003 |
| | 18. | 2003/0154032 | | Pittman et al. | 08-14-2003 |
| | 19. | 2003/0028327 | | Brunner et al. | 02-06-2003 |

| FOREIGN PATENT DOCUMENTS | | | | | | | |
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| Examiner Initials* | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | T |
| | | Office | Number | Kind Code (if known) | | | |
| | 20. | WO | 93/01205 | | The Salk Institute for Biological Studies | 1-21-1993 | |
| | 21. | WO | 94/17208 | | Xenometrix, Inc. | 4-08-1994 | |
| | 22. | WO | 97/13877 | | Lynx Therapeutics, Inc. | 04-17-1997 | |
| | 23. | WO | 99/27090 | | Smithkline Beecham Corporation | 06-03-1999 | |
| | 24. | WO | 99/43345 | | Eisai Co., Ltd.; Beth Israel Deaconess Medical Center | 09-02-1999 | |
| | 25. | WO | 99/58670 | | Cadus Pharmaceuticals Corporation | 11-18-1999 | |
| | 26. | WO | 00/12760 | | Incyte Pharmaceuticals | 9-3-2000 | |
| | 27. | WO | 01/32928 | | Phase-1 Molecular Toxicology | 05-10-2001 | |
| | 28. | WO | 01/25473 | | Source Precision Medicine, Inc. | 04-12-2001 | |

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|--------------------|-----------------|
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| | | Application Number | 09/917,800 |
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| | | First Named Inventor | MENDRICK |
| | | Group Art Unit | 1631 |
| | | Examiner Name | M. I. Miller |
| Sheet | 2 of 24 | Attorney Docket Number | GENE-035/09US |

| OTHER – NON PATENT LITERATURE DOCUMENTS | | |
|---|----------|---|
| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
| | 29. | "nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=nephrotoxic , 2 pages |
| | 30. | Aardema and MacGregor, Mutation Res., 499:13-25, (2002) |
| | 31. | Adamson & Harman et al., Biochem. Pharmacol., 45: 2289-2294 (1993) |
| | 32. | Affymetrix Rat Toxicology U34 Datasheet, released 08/99 |
| | 33. | Afshari et al., Cancer Res., 59: 4759-4760 (1999) |
| | 34. | Agha et al., Lipid Peroxidation and Lysosomal Integrity ; 31., 279-285 (1995) |
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| | 37. | Al-Bayati & Stohs, Arch. Environ. Contam. Toxicol., 20: 361-365 (1991) |
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| | 40. | Andersen & Barton, Environ. Health Perspect., 106: 349-355 (1998) |
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| | 42. | Anderson, Steven P., Hepatic Expression of Acute-Phase Protein, 26: 226-238 (1999) |
| | 43. | Andersson et al; Anthraquinone-induced cell injury; 135: 11-20 (1999) |
| | 44. | Anton et al., Cell Biochem. Biophys., 32: 27-36 (2000) Abstract only |
| | 45. | Arano et al., Arzneim-Forsch./Drug, 46 : 398-400 (1996) |
| | 46. | Atchison et al., Digestive Dis. Sci., 45: 614-620 (2000) |
| | 47. | Bajgar et al., Neurochem. Int., 24: 555-558 (1994) |
| | 48. | Baker et al., Chem. Res. Toxicol., 14(9): 1218-1231 (2001) |
| | 49. | Bandara, et al., Toxicol. Sci., 73:195-206, (2003) |
| | 50. | Barner & Gray, Ann. Pharmacother., 32: 70-77 (1998) |
| Examiner Signature | | Date Considered |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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| | | Examiner Name | M. I. Miller |
| Sheet | 3 of 24 | Attorney Docket Number | GENE-035/09US |

| OTHER – NON PATENT LITERATURE DOCUMENTS | | |
|---|----------|---|
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| | | Application Number | 09/917,800 |
| | | Filing Date | 07/31/01 |
| | | First Named Inventor | MENDRICK |
| | | Group Art Unit | 1631 |
| Examiner Name | M. I. Miller | | |
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